



**Thursdays
Plantation**

Health from Plants

**Thursdays Plantation
Laboratories Limited**

ACN 002 833 141

8 March 2001

Food and Drug Administration
5630 Fishers Lane rm. 1061
ROCKVILLE, MD 20852
USA

4581 01 MAR 20 P4:44

Dear Sir/Madam,

**Re.: Thursdays Plantation Laboratories Ltd.
Thursdays Plantation 100% Pure Tea Tree Oil
Sizes: 0.5 fl.oz, 1 fl.oz and 2 fl.oz**

We would like to request exemption from your requirements of 21CFR201.66 based on the following circumstances presented. It is impracticable due to:

1. The label sizes are too small to fit bar lines and all the wording in the font size required;
2. Should the font size be decreased, the letters bleed slightly which will cause deterioration of the text legibility.

Please find enclosed our proposed labeling in the required font size for the above product in its three pack sizes. Your advice and guidance are requested to allow us to address this problem.

Should you have any questions and need more information, you may contact our regulatory consultant, Mrs Norma Daliva-Banks at 559-346-0233, California, USA.

Your kind consideration and immediate action is greatly appreciated.

Thanking you.

Yours sincerely

**Robert Riedl
Technical Manager
Regulatory Affairs**

98N-0337

APP 15



Quality

TRIM
LINE

NDC 516-44-11

100% Pure
Thursley
Plantation

**Tea Tree Oil
Antiseptic**

0.5 fl oz (15ml)

1129864

Australian Made Product 100%

Drug Facts

Active ingredient: Tea Tree Oil 100% **Purpose:** Antiseptic

Uses: treats: ☐ minor cuts ☐ minor burns ☐ eczema ☐ abrasions ☐ insect bites ☐ scrapes

Warnings: For external use only.

When using this product:

- ☐ do not get into eyes, mouth ears or other sensitive areas of the body. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if:



- ☐ condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ☐ apply externally to the affected area. children under 12 years of age, ask a doctor.

Other information: ☐ 100% Pure Oil of Melaleuca Alternifolia. Guaranteed Activity: minimum 30% Terpinen-4-ol ☐ packaged in glass container for maximum potency, purity and activity. ☐ store at room temperature.

Thursley Plantation
Laboratories Ltd.
Bellingen, Australia.
www.thursleyplantation.com
Distributed in the USA by:
Natural Organics, Inc. Melville, NY 11747

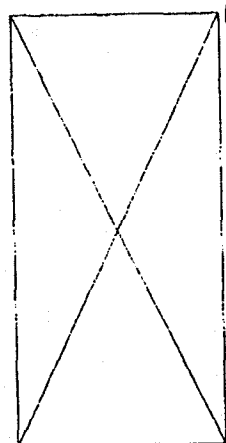
 

TEXT OUTSIDE THE
AVAILABLE LABEL
SPACE

ENLARGED 200%

1/2/01
200%

TRIM
LINE



LU5081

NDC 59165-641-15

100% Pure


Thursday
Plantation

Tea Tree Oil*
Antiseptic

0.5 fl oz (15mL)

Australian Made Product # 6400

Drug Facts

Active Ingredient:
Tea Tree Oil 100%

Purpose:
Antiseptic

Use: treats ■ minor cuts ■ minor burns
■ scrapes ■ abrasions ■ insect bites ■ stings

Warnings: For external use only.

When using this product:

■ do not get into eyes, mouth ears or other sensitive areas of the body. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if:

■ condition worsens or does not improve within 7 days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ apply externally to the affected area. children under 12 years of age, ask a doctor.

Other information: ■ *100% Pure Oil of Melaleuca Alternifolia. Guaranteed Activity: minimum 36% Terpinen-4-ol ■ packaged in glass container for maximum potency, purity and activity.
■ store at room temperature.

Thursday Plantation
Laboratories Ltd.
Ballina, Australia.



Not Tested
on Animals

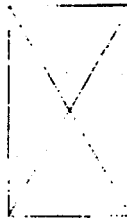
www.thursdayplantation.com

Distributed in the USA by:

Natural Organics, Inc. Melville, NY 11747

TRIM
LINE

NDC 59145-441-30



LUS091

100% Pure
Thursdays
Plantation

Tea Tree Oil
Antiseptic

1 fl oz (30mL)

Australian Made Product No. 405

Drug Facts

Active Ingredient:

Tea Tree Oil 100%

Uses: treats insect bites insect stings minor burns scrapes abrasions

Purpose:

Antiseptic

Warnings: For external use only.

When using this product:
do not get into eyes, mouth ears or other sensitive areas of the body. If contact occurs, rinse thoroughly with water.
Stop use and ask a doctor if:

condition worsens or does not improve within 7 days.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: apply externally to the affected area. children under 12 years of age, ask a doctor.

Other Information: is 100% Pure Oil of Melaleuca

Benefits: Guaranteed Activity: minimum 50% Terpinen-4-ol

is packaged in glass container for maximum potency, purity and

activity. store at room temperature.

Thursdays Plantation Laboratories Ltd. Balina,

Australia. www.thursdaysplantation.com

Distributed in the USA by:

Natural Organics, Inc. Melville, NY 11747



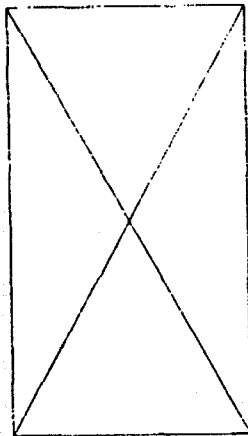
TEXT OUTSIDE
THE AVAILABLE
LABEL SPACE

ENLARGED 200%

1/2/01
200%

Trim
Line

NDC 59165-641-30



100% Pure



Thursday
Plantation

Tea Tree Oil*
Antiseptic

LUS091

1 fl oz (30mL)

Australian Made Product No. 6405

Drug Facts

Active Ingredient:

Tea Tree Oil 100%

Purpose:

Antiseptic

Use: treats ■ minor cuts ■ minor burns ■ scrapes ■ abrasions
■ insect bites ■ stings

Warnings: For external use only.

When using this product:

■ do not get into eyes, mouth ears or other sensitive areas of the body. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if:

■ condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ apply externally to the affected area. children under 12 years of age, ask a doctor.

Other information: ■ *100% Pure Oil of Melaleuca Alternifolia. Guaranteed Activity: minimum 36% Terpinen-4-ol

■ packaged in glass container for maximum potency, purity and activity. ■ store at room temperature.

Thursday Plantation Laboratories Ltd. Ballina, Australia. www.thursdayplantation.com

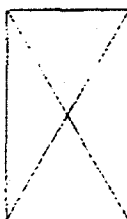
Distributed in the USA by:

Natural Organics, Inc. Melville, NY 11747



Not Tested
on Animals

TRIM
LINE →



NDC 59165-441-40

100%  Pure



Thursdays
Plantation

Tea Tree Oil*
Antiseptic

LUS040

2 fl oz (60mL)

Australian Made Product No. 6410

Drug Facts	
Active Ingredients: Tea Tree Oil 100%	Purpose: Antiseptic
Use: sores ■ minor cuts ■ minor burns ■ scrapes ■ abrasions ■ insect bites ■ stings	
Warnings: For external use only. When using this product: ■ do not get into eyes, mouth area or other sensitive areas of the body. If contact occurs, rinse thoroughly with water. ■ Stop use and ask a doctor if: ■ condition worsens or does not improve within 7 days. ■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions: ■ apply externally to the affected area. children under 12 years of age, ask a doctor.	
Other information: ■ 100% Pure Oil of Melaleuca Alternifolia. Guaranteed Activity: minimum 90% Terpinen-4-ol. ■ packaged in glass container for maximum potency, purity and activity. ■ store at room temperature.	
Thursdays Plantation Laboratories Ltd Sydney, Australia, www.thursdaysplantation.com	
Manufactured by:   Natural Organics, Inc. Melville, NY 11747	

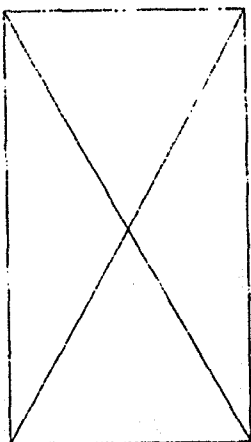
TEXT OUTSIDE
AVAILABLE
LABEL SPACE

ENLARGED 200%

1/2/01
200%

TRIM
LINE

NDC 59165-641-60



100%  Pure

**Thursday
Plantation**

Tea Tree Oil*
Antiseptic

LUS040

2 fl oz (60mL)

Drug Facts

Active Ingredient:

Tea Tree Oil 100%

Purpose:

Antiseptic

Use: treats ■ minor cuts ■ minor burns ■ scrapes ■ abrasions
■ insect bites ■ stings

Warnings: For external use only.

When using this product:

■ do not get into eyes, mouth ears or other sensitive areas of the body. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if:

■ condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: ■ apply externally to the affected area. children under 12 years of age, ask a doctor.

Other information: ■ *100% Pure Oil of Melaleuca Alternifolia.

Guaranteed Activity: minimum 36% Terpinen-4-ol ■ packaged in glass container for maximum potency, purity and activity.

■ store at room temperature.

Thursday Plantation Laboratories Ltd.

Ballina, Australia. www.thursdayplantation.com

Distributed in the USA by

Natural Organics, Inc. Melville, NY 11747

Australian Made Product No. 6410



01-02-01 THU 09:38 LEE'S FAX

07



**Thursdays
Plantation**

Health from Nature

**Thursdays Plantation
Laboratories Limited**

ABN 17 002 833 141

Pacific Highway
Ballina NSW
2478 Australia

Telephone: (02) 6686 7273
Facsimile (02) 6686 7485
International Fax: +61 2 6686 7485
email: teatree@thursdaysplantation.com
www.thursdaysplantation.com

POSTAGE
PAID
AUSTRALIA

REQUEST FOR EXEMPTION FROM 21CFR201.66 (OTC LABELING FORMAT)



**Thursdays
Plantation**

Health from Plants

**Thursdays Plantation
Laboratories Limited**

PACIFIC HIGHWAY BALLINA N.S.W. 2478

PHONE (02) 6686 7273

FAX (02) 6686 7485

TO: FOOD AND DRUG ADMINISTRATION

STREET 5630 FISHERS LANE RM. 1061

CITY ROCKVILLE, MD 20852


STATE USA POSTCODE _____

FREIGHT NOTE
NUMBER

TOTAL No.
OF ITEMS OF

FULL DETAILS PLEASE - ASSISTS EFFICIENT DELIVERY
THE ESSENCE OF EXCELLENCE

AIR MAIL
PAR AVION

 Australia Post